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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,432	12/30/2003	Charles R. Roe	BHCS:1006RCE	7856

34725 7590 06/09/2008

CHALKER FLORES, LLP
2711 LBJ FRWY
Suite 1036
DALLAS, TX 75234

EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
06/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,432	ROE, CHARLES R.	
	Examiner	Art Unit	
	Gregg Polansky	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-18 and 21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18 and 21-36* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/21/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/2008 has been entered.

2. Applicant's response, filed 4/30/2008, to the Final Rejection mailed 12/31/2007 is acknowledged. Applicants amended Claims 15, 17, and 21-29, and presented arguments in response to the Office Action.

3. Applicants' Information Disclosure Statement, filed 2/21/2008, is acknowledged and has been reviewed.

4. Claims 15-18 and 21-36 are pending and presently under consideration.

5. Applicant's arguments have been fully considered and are persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

6. The use of the trademarks TOLEREX, VIVONEX, PORTAGEN, and PREGESTAMIL have been noted in this application (for example, see page 22). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

7. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 is drawn to "[t]he method of Claim 17, wherein said triglyceride comprises triheptanoin". Claim 17 is also drawn to triheptanoin.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 15-18 and 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term "triheptanoin" in Claims 15, 17, and 30 is used by the claim to mean "a seven carbon fatty acid", while the accepted meaning is "a triglyceride of n-heptanoic acid" (indeed, the instant Specification describes triheptanoin as a triglyceride containing the saturated 7-carbon fatty n-heptanoic acid"). The term is indefinite because the Specification does not clearly redefine the term. Indeed, the instant Specification describes triheptanoin as a triglyceride containing the saturated 7-carbon fatty n-heptanoic acid.

Claim Rejections - 35 USC § 102

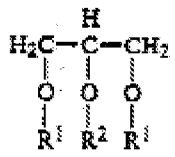
10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 15-18 and 21-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Jandacek (US Patent No. 4,753,963).

The instant claims recite a method of suppressing the effects of translocase deficiency of a human infant or pre-mature infant by administering a composition comprising triheptanoin or n-heptanoic acid, by enteral or parenteral methods. The dose of said composition comprise about 15-40% of the dietary caloric requirement for said infant.

Jandacek discloses a nutritional fat suitable for enteral and parenteral products (see abstract). The fat disclosed by Jandacek consists of triglycerides having the following formula:



wherein each R^1 group is selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl and n-undecanoyl groups; and the R^2 groups comprise from 0 to about 90% saturated acyl groups selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl and mixtures thereof; from 0 to about 90% oleoyl groups; from about 10 to 100% linoleoyl groups; and from 0 to about 10% linolenoyl groups.

When R1 and R2 are selected to be n-heptanoyl, this formula results in a nutritional fat compound that is identical to triheptanoin. The reference is drawn to developing a nutritional fat in a form which is well absorbed by those persons such as infants which have fat malabsorption problems (column 1, lines 45-48). Jandacek

teaches enteral compositions comprising the nutritional fat (triglycerides) disclosed in the reference, a source of carbohydrates, a source of amino acids and optionally, components such as vitamins and minerals. The composition can be formulated as a dry mixture or mixed with water to provide a fluid formulation for enteral administration. See column 5, lines 1-9. The amount of the triglyceride utilized in the composition is a nutritionally effective amount, based upon the subject and the nutritional benefits required. The composition typically comprises the nutritional fat (triglyceride) in an amount of about 2% to about 20% by weight of the composition (about 18 to about 180 calories per 100 grams of composition or about 4% to about 36% of the total caloric value of the composition). See column 5, lines 18-20 and column 7, lines 5-8. The reference discloses oral and feeding tube administration of the composition. See column 4, last paragraph. Jandacek also discloses parenterally administrable compositions. See column 6, lines 56-60).

Triheptanoin is metabolized by the body to three molecules of heptanoic acid and glycerol. Therefore, administration of a composition comprising triheptanoin is equivalent to administration of a composition comprising heptanoic acid. Administration of a composition/formula comprising triheptanoin would naturally suppress the effects of translocase deficiency and would naturally be metabolized by odd carbon fatty acid β-oxidation. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the

applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

Conclusion

12. Claims 15-18 and 21-36 are rejected.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1611

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/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614